

REMARKS

Applicant acknowledges receipt of the Final Office Action mailed April 21, 2010.

In the Final Office Action¹, the Examiner rejected claims 1-39 under 35 U.S.C.

§ 103(a) as being unpatentable over *Harms et al.* ("*Harms*") (U.S. Patent No. 5,364,385) in view of *Goldhaber* (U.S. Patent No. 4,396,382); and rejected claims 1-39 under 35 U.S.C. § 103(a) as being unpatentable over *Matthews* (GB Patent No. 2080116) in view of *Goldhaber*.

By this Amendment, Applicant proposes to amend claims 1, 8, 11, 12, and 39, and cancel claims 6 and 7, without prejudice or disclaimer. Claims 1-5 and 8-39 are currently pending. Claim 1 is the only pending independent claim.

The originally-filed specification, claims, abstract, and drawings fully support the amended claims 1, 8, 11, 12, and 39. No new matter has been introduced.

Applicant traverses the rejections above and respectfully requests reconsideration for at least the reasons that follow.

I. 35 U.S.C. § 103(a) REJECTIONS

Applicant traverses the rejection of claims 1-39 under 35 U.S.C. § 103(a) as being unpatentable over *Harms* in view of *Goldhaber*. Applicant respectfully disagrees with the Examiner's arguments and conclusions and submits that amended independent claim 1 patentably distinguishes over *Harms* and *Goldhaber* at least for the reasons described below. Applicant further submits that the rejections of claims 6 and 7 have been rendered moot by the cancellation of these claims.

¹ The Final Office Action contains a number of statements reflecting characterizations of the related art and the claims. Regardless of whether any such statement is identified herein, Applicant declines to automatically subscribe to any statement or characterization in the Final Office Action.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See M.P.E.P. § 2142, 8th Ed., Rev. 7 (July 2008). Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. See *id.* “A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention.” M.P.E.P. § 2145. Furthermore, “[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art” at the time the invention was made. M.P.E.P. § 2143.01(III), internal citation omitted. Moreover, “[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.” M.P.E.P. § 2141.02(I), internal citations omitted (emphasis in original).

“[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). . . . The factual inquiries . . . [include determining the scope and content of the prior art and] . . . [a]scertaining the differences between the claimed invention and the prior art.” M.P.E.P. § 2141(II). “Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.” M.P.E.P. § 2141(III).

Amended independent claim 1 recites a fluid bag, “the fluid bag being at least partly made of flexible material, said fluid bag having a first main sheet and a second

main sheet configured opposite to said first main sheet, an extension of said first main sheet being limited by a first boundary, an extension of said second main sheet being limited by a second boundary, . . . wherein one or more distance limiting members limit the distance between said first and second main sheets by extending to the first and second boundaries of the first and second main sheets, respectively."

Harms appears to disclose a bag disclosed for the collection, freezing, storage, and rapid thawing of fluids, and particularly blood and blood components. Front and back sheets of fluid impervious material are bonded to one another along edge portions thereof to form a bag defining a reservoir. The front and back sheets are further bonded together at a plurality of locations intermediate the edge portions to constrain the distance by which the front and back sheets can separate. A port is provided for introducing and discharging fluid into and out of the reservoir. (*Harms*, Abstract).

Applicant points out that the Examiner concedes that "*Harms* discloses that the bag contains blood products, not dialysis fluids as claimed by Applicant." (*Final Office Action*, p. 3, ll. 1-2). *Harms* also fails to teach or suggest "the fluid bag being at least partly made of flexible material, said fluid bag having a first main sheet and a second main sheet configured opposite to said first main sheet, an extension of said first main sheet being limited by a first boundary, an extension of said second main sheet being limited by a second boundary, . . . wherein one or more distance limiting members limit the distance between said first and second main sheets by extending to the first and second boundaries of the first and second main sheets, respectively."

The blood bag 10 in *Harms* includes seal lines 60 for constraining the expansion of the filled bag 10. (*Harms*, col. 6, ll. 61-63). The seal lines 60, however, do not

extend to the boundaries of the front and back sheets 11, 12, respectively, as is required by amended independent claim 1.

As disclosed on page 14, lines 26-31 of Applicant's specification, "the distance limiting members 40 [of the claimed invention] are formed by welds . . . [T]he welds 40 reach all the way to the boundaries of the first 14 and second 16 sheets."

In order to cure the deficiencies of *Harms*, the Examiner relies on *Goldhaber* and contends that "Goldhaber discloses a flexible bag that may contain fresh and spent dialysis fluid." (*Office Action*, p. 4, ll. 3-4).

Goldhaber appears to disclose "a solution bag formed of three plastic walls sealed together about their peripheries to define a pair of separate chambers for peritoneal dialysis and the like." (*Goldhaber*, Abstract). *Goldhaber*, however, fails to teach or suggest at least a fluid bag, "the fluid bag being at least partly made of flexible material, said fluid bag having a first main sheet and a second main sheet configured opposite to said first main sheet, an extension of said first main sheet being limited by a first boundary, an extension of said second main sheet being limited by a second boundary, . . . wherein one or more distance limiting members limit the distance between said first and second main sheets by extending to the first and second boundaries of the first and second main sheets, respectively," as recited in amended independent claim 1.

Goldhaber discloses a solution bag 10 formed of three flexible plastic walls 12, 14, and 16 sealed together about their peripheries 18 to define a pair of separate chambers 20 and 22. (*Goldhaber*, col. 4, ll. 16-19). The solution bag 10, however, fails

to include one or more distance limiting members that limit a distance between the sheets of the solution bag 10 by extending to the boundaries of the sheets.

As explained above, the elements of amended independent claim 1 are neither taught nor suggested by the cited references. Consequently, in the Final Office Action the Examiner has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claim. Accordingly, no sufficient reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 1 and this claim is allowable over the cited references. Claims 2-5 and 8-39 are also allowable over *Harms* and *Goldhaber*, due at least to their dependence from allowable independent claim 1, and due to their additional recitations of novel subject matter. Applicant therefore requests that the rejection of claims 1-39 under 35 U.S.C. § 103(a) be withdrawn.

Applicant also traverses the rejection of claims 1-39 under 35 U.S.C. § 103(a) as being unpatentable over *Matthews* in view of *Goldhaber*. Applicant respectfully disagrees with the Examiner's arguments and conclusions and submits that amended independent claim 1 patentably distinguishes over *Matthews* and *Goldhaber* at least for the reasons described below. Applicant further submits that the rejections of claims 6 and 7 have been rendered moot by the cancellation of these claims.

As discussed above, amended independent claim 1 recites a fluid bag, "the fluid bag being at least partly made of flexible material, said fluid bag having a first main sheet and a second main sheet configured opposite to said first main sheet, an

extension of said first main sheet being limited by a first boundary, an extension of said second main sheet being limited by a second boundary, . . . wherein one or more distance limiting members limit the distance between said first and second main sheets by extending to the first and second boundaries of the first and second main sheets, respectively."

Matthews appears to disclose a drainage bag for wear as a urine collection bag. The bag has front and rear walls 10, 12 of plastic material welded together to form a peripheral seam 16. The front and rear walls are further joined together by closed loop welds 20 inside the area enclosed by the peripheral seam. The bag preferably has 3-10 closed loop welds. These welds prevent bulging of the bag when it is full of liquid. (*Matthews*, Abstract).

The Examiner concedes, however, that "Matthews discloses that the bag contains waste products, not dialysis fluids as claimed by Applicant." (*Final Office Action*, p. 6, ll. 7-8). *Matthews* also fails to teach or suggest a fluid bag, "the fluid bag being at least partly made of flexible material, said fluid bag having a first main sheet and a second main sheet configured opposite to said first main sheet, an extension of said first main sheet being limited by a first boundary, an extension of said second main sheet being limited by a second boundary, . . . wherein one or more distance limiting members limit the distance between said first and second main sheets by extending to the first and second boundaries of the first and second main sheets, respectively."

The drainage bag in *Matthews* includes closed loop welds 20 distributed over the area of the sheets 10 and 12 to prevent undue bulging of the bag when it is full of liquid. (*Matthews*, p. 1, ll. 50-64). The closed loop welds 20, however, do not extend to the

boundaries of the sheets 10, 12, respectively, as is required by amended independent claim 1. Thus, *Matthews* fails to disclose "distance limiting members limit the distance between said first and second main sheets by extending to the first and second boundaries of the first and second main sheets, respectively," as recited in amended independent claim 1.

As disclosed on page 14, lines 26-31 of Applicant's specification, "the distance limiting members 40 [of the claimed invention] are formed by welds . . . [T]he welds 40 reach all the way to the boundaries of the first 14 and second 16 sheets."

In order to cure the deficiencies of *Matthews*, the Examiner relies on *Goldhaber* and contends that "Goldhaber discloses a flexible bag that may contain fresh and spent dialysis fluid." (*Office Action*, p. 7, ll. 6-7).

As discussed above, *Goldhaber* appears to disclose "a solution bag formed of three plastic walls sealed together about their peripheries to define a pair of separate chambers for peritoneal dialysis and the like." (*Goldhaber*, Abstract). *Goldhaber*, however, fails to disclose or suggest at least a fluid bag, "the fluid bag being at least partly made of flexible material, said fluid bag having a first main sheet and a second main sheet configured opposite to said first main sheet, an extension of said first main sheet being limited by a first boundary, an extension of said second main sheet being limited by a second boundary, . . . wherein one or more distance limiting members limit the distance between said first and second main sheets by extending to the first and second boundaries of the first and second main sheets, respectively," as recited in amended independent claim 1.

Goldhaber discloses a solution bag 10 formed of three flexible plastic walls 12, 14, and 16 sealed together about their peripheries 18 to define a pair of separate chambers 20 and 22. (*Goldhaber*, col. 4, ll. 16-19). The solution bag 10, however, fails to include one or more distance limiting members that limit a distance between the sheets of the solution bag 10 by extending to the boundaries of the sheets.

As explained above, the elements of amended independent claim 1 are neither taught nor suggested by the cited references. Consequently, in the Final Office Action the Examiner has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claim. Accordingly, no sufficient reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 1 and this claim is allowable over the cited references. Claims 2-5 and 8-39 are also allowable over *Matthews* and *Goldhaber*, due at least to their dependence from allowable independent claim 1, and due to their additional recitations of novel subject matter. Applicant therefore requests that the rejection of claims 1-39 under 35 U.S.C. § 103(a) be withdrawn.

II. CONCLUSION

Applicant requests the Examiner's reconsideration and reexamination of the application, and the timely allowance of pending claims 1-5 and 8-39.

Applicant respectfully points out that the final action by the Examiner presented some new arguments as to the application of the art against Applicant's claims. It is

respectfully submitted that the entering of the Amendment would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

Applicant further submits that the entry of the Amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicant submits that this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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